DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 21, 2014

Siemens Medical Solutions USA, Inc.
% Mr. Ken Duplantis
Regulatory Affairs
757 "A" Arnold Drive
MARTINEZ CA 94553

Re: K142434
Trade/Device Name: ARTISTE Solution, Sys_VC10C Phase 2 update, with the syngo RT Therapist and RT Oncologist Workspaces, v4.3.1_MR1 update
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: II
Product Code: IYE
Dated: August 23, 2014
Received: August 29, 2014

Dear Mr. Duplantis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142434

Device Name
ARTISTE™ Solution, SYS_VC10C, Phase 2 Update with the syngo® RT Therapist & RT Oncologist Workspaces, v4.3.1_MR1

Indications for Use *(Describe)*
The intended use of the SIEMENS branded ARTISTE™, ONCOR™ and PRIMUS™ family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer.

The linear accelerator systems are high-dose and high-dose rate medical linear accelerators optimized for 3D conformal radiation therapy, intensity-modulated radiation therapy (IMRT), modulated arc therapy (mARC) and precision stereotactic radiation therapy for lesions, tumors and conditions anywhere in the head and body where radiation therapy is indicated.

The syngo® RT Therapist Workspace is a component of the linear accelerator system and is based on the syngo® architecture. The syngo® RT Therapist workspace contains software applications to support patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording.

The syngo® RT Oncologist Workspace is an optional accessory to the linear accelerator system and permits localization, contouring, segmentation, image review, and review and approval of treatment plan parameters. In addition, it includes tools and administrative functions to aid in the diagnosis, staging, and prescription of radiation therapy.

The syngo® RT Therapist and the syngo® RT Oncologist Workspaces v4.3.1_MR1, can be interfaced with third party OIS, V&R, TPS, and PACS devices conforming to the DICOM Standard.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Section 5

510(k) Summary

Date Prepared: **August 20, 2014**

Submitter: Siemens Medical Solutions USA, Inc.
Radiation Oncology
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Contact: Christine Dunbar
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Proprietary Name: ARTISTE with Sys_VC10C, Phase 2 update, including the *syngo*® RT Therapist Workspace, v4.3.1_MR1 Update *syngo*® RT Oncologist Workspace, v4.3.1_MR1 Update

Common Name: Medical Charged-Particle Radiation Therapy System

Classification: 892.5050

Product Code: IYE

Substantial Equivalence Claimed To (21 CFR §807.92(a)(3))

Product	510(k) Clearance / Date	Claim of Equivalence for:
ARTISTE™ Solution with SYS-VC10C, Phase 1 for the syngo® RT Therapist (RTT v4.3.1, CC 13.0.112) supporting 3rd party OIS, V&R, TPS, and PACS.	K132935 / Feb. 21, 2014	ARTISTE™ Solution with SYS-VC10C, Phase 2 update for the syngo® RT Therapist (RTT v4.3.1_MR1, & CC 13.0.301) supporting 3rd party OIS, V&R, TPS, and PACS and new CC feature Automatic Movement Protection. Additionally, serves as a predicate for the hosting of third party OIS on the syngo® based workspaces, the syngo® RT Oncologist v4.3.1_MR1.

ARTISTE™ Solution with SYS-VC10A for the syngo® RT Therapist (RTT v4.3, CC 13.0.65) supporting 3rd party OIS, V&R, TPS, and PACS. & syngo® RT Oncologist v4.3 with VSim v2.7	K121295 / June 12, 2012	ARTISTE™ Solution with SYS-VC10C, Phase 2 update for the syngo® RT Therapist (RTT v4.3.1_MR1 & CC 13.0.301) supporting 3rd party OIS, V&R, TPS, and PACS. & syngo® RT Oncologist v4.3.1_MR1 and the VSim v2.7 module.
Product	**510(k) Clearance / Date**	**Claim of Equivalence for:**
ARTISTE™ Solution with SYS-VC10C, Phase 1 for the *syngo*® RT Therapist (RTT v4.3.1, CC 13.0.112) supporting 3rd party OIS, V&R, TPS, and PACS. Sys_VC10A update backwards compatible and an optional upgrade for the ONCOR and PRIMUS systems.	K132935 / Feb. 21, 2014	ARTISTE™ Solution with SYS-VC10C, Phase 2 for the *syngo*® RT Therapist (RTT v4.3.1x, CC 13.0.301) supporting 3rd party OIS, V&R, TPS, and PACS. Sys_VC10C, version RTT 4.3.1x is backwards compatible and is an optional upgrade for the ONCOR and PRIMUS systems.
ARTISTE™ Solution with SYS-VC10A for the *syngo*® RT Therapist (RTT v4.3, CC 13.0.65) supporting 3rd party OIS, V&R, TPS, and PACS. And *syngo*® RT Oncologist v4.3 with VSIM v2.7 with Siemens OIS. Sys_VC10A update is backwards compatible and is an optional upgrade for the ONCOR and PRIMUS systems.	K121295 / June 12, 2012	ARTISTE™ Solution with SYS-VC10C, Phase 2 for the *syngo*® RT Therapist (RTT v4.3.1_MR1, CC 13.0.301) supporting 3rd party OIS, V&R, TPS, and PACS. And *syngo*® RT Oncologist v4.3.1x with VSIM v2.7 and third party OIS Sys_VC10C, RTT and ONC version 4.3.1_MR1 is backwards compatible and is an optional upgrade for the ONCOR and PRIMUS systems.

The update to the ARTISTE Linear Accelerator's Control Console, the *syngo*® RT Therapist Workspace, v4.3.1_MR1 and the *syngo*® RT Oncologist Workspace, v4.3.1_MR1 as described in this premarket notification has the same intended use, indications for use, and fundamental scientific technical characteristics as the predicate devices listed above.

Description Summary (21 CFR §807.92(a)(4))

ARTISTE™ Solution Linac with Control Console v13.0.301, including the *syngo*® RT Therapist Workspace v4.3.1_MR1, and the *syngo*® RT Oncologist Workspace v4.3.1_MR1 Updates

The project Sys_VC10C, Phase 2 software update for the ARTISTE™ Solution linear accelerator system with Control Console v13.0.301 with the *syngo*® RT Therapist Workspace v4.3.1_MR1 release is intended to update customers with the currently cleared and released *syngo*® RT Therapist Workspace software with versions v4.1, v4.2, v4.3 or v4.3.1 for ARTISTE, and is backwards compatible with the ONCOR & PRIMUS Linear Accelerator systems with the COHERENCE RT Therapist v2.3. The currently cleared *syngo*® RT Therapist workspace software v4.3.1 supports Siemens branded and third party OIS, V&R, TPS, and PACS systems.

Additionally, the Phase 2 software update includes software modifications and defect fixes for the *syngo*® RT Oncologist workspace. The Oncologist software is developed on the same *syngo*® software code platform as the RT Therapist and the workspace differentiation is license key controlled for clinically focused workspace options. The *syngo*® RT Oncologist workspace is considered a medical device in its own right had has multiple previous FDA 510(k) clearances.

Note: Several *syngo*® clinical modules are considered medical devices in their own right and may have separate clearances. For example, the *syngo*® VSim module, v2.7 received FDA clearance under K101119 and is licensed on several *syngo*® workspaces for different modalities. The *syngo*® RT Oncologist Workspace has hosted this module under multiple clearances with the latest being the current predicate, K121295.

These previous software versions can be directly migrated to the current release (*syngo*® RTT/ONC v4.3.1_MR1) and Control Console v13.0.301. The ARTISTE Solution with VC10C, Phase 1 and the *syngo*® RT Therapist v4.3.1 cleared under K132935 serves as a predicate in this submission.

The *syngo*® RT Oncologist workspace is an optional system for Siemens Linac customers. The *syngo*® RT Oncologist also hosts software based products such as the VSim v2.7 feature [VSIM] and other oncology based features. The *syngo*® RT Oncologist workspace v4.3 was previously cleared under K121295 which serves as a predicate in this submission.

The technological characteristics and the fundamental technology of the LINAC Control Console and the *syngo*® RT Therapist Workspace v4.3.1_MR1 and the *syngo*® RT Oncologist Workspace v4.3.1_MR1 (including the *syngo*® VSim module) remain unchanged from the currently cleared products. This is a software update only. The materials of use remain unchanged from the predicate devices.

Risk Management and General Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software means, user instructions, verification of requirements and validation of the clinical workflow to ensure that the product meets its intended uses. To minimize electrical, mechanical and radiation hazards, SIEMENS adheres to recognized and established industry practice and relevant international standards.

Refer to Section 21 for the Risk Management documentation.

Intended Use / Indications for Use (21 CFR §807.92(a)(5))

The intended use of the SIEMENS branded ARTISTE™, ONCOR™ and PRIMUS™ family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer.

The linear accelerator systems are high-dose and high-dose rate medical linear accelerators optimized for 3D conformal radiation therapy, intensity-modulated radiation therapy (IMRT), modulated arc therapy (mARC) and precision stereotactic radiation therapy for lesions, tumors and conditions anywhere in the head and body where radiation therapy is indicated.

The syngo® RT Therapist Workspace is a component of the linear accelerator system and is based on the syngo® architecture. The syngo® RT Therapist workspace contains software applications to support patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording.

The syngo® RT Oncologist Workspace is an optional accessory to the linear accelerator system and permits localization, contouring, segmentation, image review and review and approval of treatment plan parameters. In addition, it includes tools and administrative functions to aid in the diagnosis, staging, and prescription of radiation therapy.

The syngo® RT Therapist and the syngo® RT Oncologist Workspaces v4.3.1_MR1, can be interfaced with third party OIS, V&R, TPS, and PACS devices conforming to the DICOM Standard.

Technological Characteristics and Substantial Equivalence (21 CFR §807.92(a)(6)):

The Substantial Equivalence comparison chart (Section 12) demonstrates the comparison of the technological characteristics of the *syngo*® RT Therapist Workspace, the *syngo*® RT Oncologist Workspace, and the LINAC Control Console v13 to their currently cleared predicate versions.

The *syngo*® RT Therapist Workspace v4.3.1_MR1 (project Sys_VC10C, Phase 2) does not change the intended use or Indications for Use of the original ARTISTE™ Solution Linac with the *syngo*® RT Therapist Workspace v4.3.1 (project Sys_VC10C, Phase 1) or the previously cleared ONCOR™ or PRIMUS™ Siemens branded Linear Accelerator Systems.

The *syngo*® RT Oncologist Workspace v4.3.1_MR1 (project Sys_VC10C, Phase 2) does not change the Intended Use or Indications for Use of the currently cleared *syngo*® RT Oncologist Workspace v4.3. (Sys_VC10A, K121295).

Summary of Verification and Validation Activity (21 CFR §807.92(b)):

Bench Testing (21 CFR §807.92(b)(1))

Bench testing in the form of Unit, Integration and System Integration testing was performed to evaluate the performance and functionality of the software update v4.3.1_MR1 for the RT Therapist and RT Oncologist software and regression testing the Control Console version 13.0.301.

All testable requirements in the System Requirements Specifications (SRS), Sub-system Requirements Specifications (SSRS) and Component Requirements (CRS) for the Sys_VC10C project, Phase 2, and additionally the specific requirements for the implementation of the third party OIS have been successfully verified and traced in accordance with the Siemens product development (lifecycle) process (PDP) described in Section 11.

The software verification and regression testing has been performed successfully to meet their previously determined acceptance criteria as stated in the Test Concept.

Non-Clinical Test Results (21 CFR §807.92(b)(2))

Validation of the *syngo*® RT Therapist Workspace v4.3.1_MR1, the *syngo*® RT Oncologist Workspace v4.3.1_MR1 with the hosting of the optional third party OIS and regression testing with Control Consoles 13.0.301 has been performed at the System test level on production prototype devices by appropriately trained and knowledgeable test personnel, therefore, clinical testing is not required. System level validation and regression testing has been performed successfully, demonstrating that the software meets the acceptance criteria as noted in the system test plans.

Testing to Consensus Standards (21 CFR §807.92(b)(1))

The *syngo*® RT Therapist Workspace v4.3.1_MR1, the *syngo*® RT Oncologist Workspace v4.3.1_MR1 and the Control Console 13.0.301 update have been tested (as needed) to meet the requirements for conformity (where applicable) to multiple industry standards. The R&D evaluation of the relevant testing to consensus standards is documented.
Refer to Section 9 for this documentation.

Substantial Equivalence to Predicates (21 CFR §807.92(b)(1))

The verification testing to the system requirements (SRS) for the *syngo*® RT Therapist v4.3.1_MR1 and the RT Oncologist v4.3.1_MR1 workspaces, validation of the intended use, and the regression testing to the existing *syngo*® RT Therapist / Oncologist software and Control Console v13.0.301 functional requirements, is intended to support the claim of substantial equivalence to the following predicates:

- The ARTISTE™ Solution with SYS-VC10A for the *syngo*® RT Therapist (RTT v4.3, CC 13.0.65) supporting 3rd party OIS & V&R (MOSAIQ and Sequencer V&R[1]) and third party TPS and PACs systems. Additionally, the *syngo*® RT Oncologist workspace (ONC v4.3 with VSIM v2.7), (K121295). Primary predicate for the *syngo*® RT Oncologist workspace v4.3.1 MR1 updates including VSim v2.7 bug fixes, and support for the third party OIS connectivity.

- The ARTISTE™ Solution with SYS-VC10C for the *syngo*® RT Therapist (RTT v4.3.1, CC 13.0.112) supporting 3rd party OIS & V&R (ARIA and Varian Treat V&R[2]) and third party TPS and PACs systems. (K132935). Primary predicate for the *syngo*® RT Therapist workspace v4.3.1 MR1 with Control Console v13.0.301 / FC updates and support for the third party OIS connectivity.

[1] MOSAIQ OIS and Sequencer V&R systems are manufactured by IMPAC Medical / Elekta AB.
[2] ARIA OIS and Varian Treatment console are manufactured by Varian Medical Systems.

510(k) Summary (21 CFR §807.92(c))

In summary, based on the successful verification and validation testing to the software acceptance criteria, it is SIEMENS' opinion that the *syngo*® RT Therapist Workspace update to v4.3.1_MR1 including the update to the LINAC Control Console v13.0.301 to support the new Automatic Movement Protection feature and the *syngo*® RT Oncologist Workspace update to v4.3.1_MR1, including hosting of the optional 3rd party OIS and bug fixes, does not introduce any new potential safety risks and are substantially equivalent to, and performs as well as, the predicate devices.

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